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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,216	11/19/2003	Scott Salys	A03P1076	9041
36802	7590	10/19/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			FAULCON JR, LENWOOD	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/718,216	SALYS ET AL.
	Examiner	Art Unit
	Lenwood Faulcon, Jr.	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-7,9-13 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-7,9-13 and 15-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-7, 9-13 and 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doan et al. (U.S. Patent No. 5,456,708) in view of Giele et al. (U.S. Patent No. 5,575,814)

Doan et al. teaches of an implantable flexible lead assembly, comprising a screw-in helix electrode for extending and contracting (col. 2 lines 64-67), a flexible electrically conductive coil housed within an insulating tube (col. 4 lines 41-44), a radiopaque ring (collar) at the distal tip of the lead (col. 3 lines 1-4). Doan et al. further teaches of the radiopaque ring being fabricated of a biocompatible, biostable metallic such as a platinum/iridium alloy. Doan et al. also teaches of a helical shaft being electrically and mechanically coupled to a rotatable connector pin (col. 4 lines 41-44), in which the connector pin effectuates lead fixation or removal (col. 2 lines 23-27). Doan et al. further teaches that it is well known in the art that in conductors couple connector pins to electrodes (col. 1 lines 38-41). Doan et al. also teaches that the helix electrode may be made of a platinum/iridium alloy, which is inherently a radiopaque material.

Giele et al. teaches of an active fixation medical electrical lead having mapping capability, compromising a low-threshold, high-impedance, screw-in endocardial pacing

lead (col. 2 lines 9-10) with an extending and contracting fixation helix (col. 2 lines 30-35). Giele et al. also teaches of the lead body consisting of two coaxial, elongate flexible sheaths, inner and outer (col. 2 lines 12-13). Giele et al. further teaches of the lead body (12) comprising an outer insulative sheath (32) that houses an inner conductor (34). Giele et al. also teaches that the inner conductor extends the length of the lead body and is also housed by an electrically conductive tube (37) at its distal end. Giele et al. further teaches of the use of a distal helix-engaging collar (46) and mapping by fluoroscopic techniques (col. 7 lines 5-9).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Doan et al. with the teachings of Giele et al. Doan et al. and Giele et al. both teach of medical leads for electrical stimulation, and thus teach of analogous arts. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Doan et al. to include an electrically conductive tube for housing the helical fixation element, in order to facilitate movement of electricity along the lead. Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the conductive tube as taught by Giele et al. by having the tube comprise a conductive metal alloy such as MP35N, since Giele et al. teaches of the use MP35N for the lead conductor (col. 4 lines 7-8).

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bisping (U.S. Patent No. 4,106,512), McArthur (U.S. Patent No.

4,649,938), Peers-Travarton (U.S. Patent No. 4,667,686), Holleman et al. (U.S. Patent No. 5,003,992), Li. (U.S. Patent No. 5,259,395), Morris (U.S. Patent No. 5,374,286), Hoff (U.S. Patent No. 5,522,872), Li (U.S. Patent No. 5,716,390).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lenwood Faulcon, Jr.


George Manuel

Primary Examiner